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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/20/2005

Benjamin Geller

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67801

7590

07/22/2010

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EXAMINER

GUPTA, VANI

ART UNIT

PAPER NUMBER

3768

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/553,933	Applicant(s) GELLER ET AL.	
	Examiner VANI GUPTA	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 28, 29 and 33-55 is/are pending in the application.
- 4a) Of the above claim(s) 28, 29, 33, 34 and 41-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 36-40 and 45-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. ***Claims 1 - 3, 35 – 37, 39, 45 – 48 and 53 – 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Iger et al. (US 6,206,843 B1).***

Regarding claims 1, 45 – 48, 51, Iger et al. discloses an apparatus for the ultrasonic treatment of tissue, including: a housing – flexible, “elastomeric,” cone – having a space therewithin and an opening adapted for placement against the tissue, the housing being adapted for introducing liquid therein such that when so placed, the space is filled with liquid (***claim 48***); an (***with respect to claims 51, 52***) ultrasonic power source (“transducer”) (***21***) within holder (***22***) that introduces ultrasonic vibrations toward the tissue, said vibrations having a frequency and power level sufficient to produce cavitations of the liquid at or near the surface of the tissue (***figs. 2 – 4; col. 5, line 22 – col. 6, line 17; and col. 8, line 29 – col. 10, line 25***); and (***with respect to claim 45***) an “elastomer” interface (interface between “acoustic lens” as well as proximal wall of “container”) capable of transferring acoustic energy – therefore, inherently comprising acoustic properties similar to the acoustic liquid – separating the ultrasonic power source from the liquid (***fig. 1. #12 and 13; col. 6, line 67 - col. 7, line 1; col. 8, ll. 34 – 36***). As discussed by Iger et al., the acoustic lens is made of plexiglass and (***with respect to claim 46***) the container made of

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flexible material – both of which are elastic or elastomeric in nature. Most, if not all, known materials are elastic to some degree.

Regarding claims 2 and 3, Iger et al. discloses that the opening of the apparatus comprises a sealing element that provides a seal at the tissue. That is to say, based on the figure, the opening is inherently a sealant when placed against the skin surface. The seal includes a flexible element, given that the opening lies at the tapered end of the flexible container (**fig. 1, #16 and 14**).

Regarding Claim 35, Iger et al. discloses that the source of acoustic energy includes ultrasonic energy concentrator (“*acoustic lens*,” **fig. 1, 12; col. 3, ll. 44 – 45; col. 7, ll. 7 – 11**). Or, the generator itself could behave as a concentrator (**col. 5, ll. 37 – 38**).

Regarding Claim 36, Iger et al. discloses that the interface is part of the housing (“*acoustic lens*,” **fig. 1, 12 and 13; and rejection of Claim 1**).

Regarding Claim 37, Iger et al. discloses that the interface comprises an elastic barrier (**rejection of Claim 1**).

Regarding Claim 39, Iger et al. discloses that at least a portion of the interface acoustically matches the liquid to an extent that prevents cavitation at the interface between the liquid and the interface, since the interface is an “acoustic lens” and the liquid is an “acoustic coupling medium” (**fig. 12 - lens; and col. 9, ll. 3 - 5**).

Regarding Claim 52, Iger suggests that the transducer is capable of transmitting ultrasonic energy in an amount that causes desired cavitation at the surface of the tissue. That is, Iger provides high intensity frequencies sufficient enough to cause cavitation bubbles (**fig. 1, 11; fig. 2, 21; col. 6, ll. 15- 17; col. 10, ll. 29 – 30**).

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Regarding claims 53 - 55, Iger suggests capabilities for, regardless of what it may be called, for introducing liquid into the housing and removing liquid from the housing (*col. 6, ll. 9 - 11; col. 9, ll. 41 - 43*). That is, if Iger is capable of inletting liquid, as discussed in cited passages, then Iger is also capable of outletting liquid. Iger also suggests capabilities for, regardless of what it may be called, liquid inletting and liquid outletting, capable of being placed in the housing on opposite sides of an area of the skin to be treated, so that the liquid flows across the area (*as shown in figs. 3A - 4B*).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 4 - 7 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iger et al. (US 6,206,843 B1).

Regarding claims 4 - 7, Iger et al. discloses the apparatus of Claim 1 that comprising a flexible sealing element, except for wherein the seal includes an inwardly or outwardly protruding portion that is placed to contact the tissue surface. However, it would be have been obvious matter of design choice to include either arrangement, since applicant has not disclosed that either arrangement solves an stated problem or is for any particular purpose and it appears that the invention would perform equally well with any of the arrangements provided by Iger et al. in *figs. 1 - 4* to ensure optimal contact and sealing with the skin surface of a patient.

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Regarding Claim 38, Iger et al. discloses that the elastic barrier of the apparatus of Claim 1 is made of a hard plastic such as plexiglass (see rejection of Claim 1), instead of polyurethane. However, Iger et al. explains that the lens is flexible enough that its curvature capable of change (col. 7, line 65 – col. 8, line 2) and is acoustic in nature (col. 7, ll. 7 – 9), much as a polyurethane material is capable of as required by disclosure of present application. Therefore, it would be obvious to one of ordinary skill to substitute one material for the other.

3. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Iger et al. (US 6,206,843 B1) as applied to claim 1 above, and further in view of Derman et al. (US 6,378,376 B1).

Regarding Claim 40, Iger et al. discloses the apparatus of Claim 1, wherein the housing comprises that the liquid-holding container is removable (col. 7, ll. 15 – 18).

However, Iger et al. differs from claim 40 in that Iger et al. does not specifically suggest that container is sterilizable or cleanable.

Nonetheless, Derman et al. teaches that parts of an ultrasound transducer may removable for cleaning or replacing (col. 3, ll. 60 – 63; and col. 4, ll. 30 - 31).

Accordingly, it would have been prima facie obvious to modify Iger et al. with Derman et al., because one of ordinary skill in the art would be aware that this capability is of utmost importance to prohibit cross-contamination between patients and for optimal performance as well.

4. Claims 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iger as applied to claim 1 above, and further in view of Babaev (US 6,478,754 A1).

Regarding Claim 49, Iger discloses the apparatus of Claim 1, as discussed above.

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However, Iger does not suggest specifically the liquid is one of a saline or a detergent.

Nonetheless, Babaev teaches ultrasound coupling fluid comprising saline (*col. 6, ll. 23 – 25*).

Accordingly, it would have been *prima facie* obvious to modify Iger with Babaev for effective way to remove containments on the skin during the procedure (*Babev; col. 3, ll. 12 – 15*).

Regarding Claim 50, Babaev suggests that the liquid comprises medication (*col. 6, ll. 23 – 25; col. 7, ll. 11 – 14*).

Response to Arguments

5. *Applicant's arguments filed April 1, 2010 have been fully considered but are not persuasive.*

Applicant argues that Iger's interface, as a focusing lens, is not flat but rather has a curvature; for example, in Col. 8 Lines 35-36 “an acoustic lens., having a curvature ‘r’.”

Examiner respectfully disagrees and points out that Figure 1 indicates that this lens **(12)** is flat on the side that “interfaces” with the ultrasound transducer **(11)**. Therefore, Iger still meets the claim.

Transducer **(11)** is within “receptacle” or transducer-housing as shown in **Figure 1**; as transducer **(21)** within holder **(22)** as shown in **figure 2**. Please see above rejections of claim 1, etc., for citation of figures 2 - 4 and passages within *col. 8, line 29 – col. 10, line 25 (namely, col. 9, ll. 1 – 3)* for teachings of these features of Claim 1 and other claims.

Arguments with respect to rejections of dependent claims are moot in light of above response(s).

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANI GUPTA whose telephone number is (571)270-5042. The examiner can normally be reached on Monday - Thursday (8:30 am - 6:00 pm; EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/V. G./
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768